K001121

NOV 2 9 2001

510(k) NOTIFICATION SUMMARY
(Per 21 CFR 807.92)

Prepared: 16 March 2000

TRADE NAME: Oxygen Applied Symptom Improvement System (OASIS)

COMMON NAME OF DEVICE: Multiplace Hyperbaric Chamber

CLASSIFICATION: 73 CBF, 21 CFR 868.5470

ESTABLISHMENT REGISTRATION NUMBER: 1650365

CLAIMED PREDICATE DEVICE(S):

Tampa Hyperbaric Enterprises' Multiplace Hyperbaric Chamber – K960389
Perry Sigma MP Multiplace Hyperbaric Chamber – K930748
Gulf Coast Hyperbarics Multiplace Hyperbaric Chamber – K 950957
Reimers T Class Hyperbaric Facility – K95438

ADDRESS OF MANUFACTURER:

Engineered Medical Technology, Inc.
7303 Houston Highway
PO Box 1939
Victoria, TX 77902
(361) 578-3551

CONTACT PERSON: Gerado L. (Vic) Cantu

EXECUTIVE SUMMARY

The Undersea and Hyperbaric Medical Society (UHMS) defines hyperbaric oxygen therapy as breathing 100% oxygen at pressures higher than atmospheric in a hyperbaric chamber. According to the National Fire Protection Association (NFPA), hyperbaric chambers are classified into two categories: Class A (multi-occupant) and Class B (single occupant). The EMT Oxygen Applied Symptom Improvement System (OASIS) is a Class A monoplace hyperbaric chamber designed to treat up to 20 patients at up to a maximum operating pressure of 6 Atmospheres Absolute (ATA) or 73.5 pounds per square inch gauge (psig). The chamber uses compressed air as the pressurization gas and 100% oxygen as the hyperbaric treatment gas.

The EMT OASIS is intended to be procured and used by physicians to treat a variety of medical conditions that respond to hyperbaric oxygen. The UHMS produces a list of medical conditions that have been identified for the appropriate primary or adjunctive use of hyperbaric oxygen. These approved conditions include: air or gas embolism; carbon monoxide poisoning and carbon monoxide poisoning complicated by cyanide poisoning; clostridial myositis and myonecrosis (gas gangrene); crush injury, compartment syndrome and other acute traumatic ischemias; decompression sickness; enhanced healing of selected problem wounds; exceptional blood loss anemia; necrotizing soft tissue infections; osteomyelitis (refractory); delayed radiation injury (soft tissue and bony necrosis); compromised skin flaps and grafts; thermal burns; and, intracranial abscess. Aggressive

research into the beneficial effects of hyperbaric oxygen, when appropriately applied, will result in additional medical conditions being added to the list of indications by the UHMS.

The EMT OASIS is designed and fabricated in accordance with the requirements of the ANSI/ASME Boiler and Pressure Vessel Code, Section VIII, Division 1, Pressure Vessels; ANSI/ASME-PVHO-1 (American Society of Mechanical Engineers-Pressure Vessels for Human Occupancy); and, NFPA 99, Health Care Facilities, Chapter 19, Hyperbaric Facilities. The overall external length of the chamber can range from 28 feet to 36 feet. Its internal diameter can range from 84 inches to 108 inches. When combined, these features allow for the state of the art, hands on treatment of eight (8) to 20 ambulatory patients in comfort. Large circular windows create a more open atmosphere and help reduce patient claustrophobia. Pressurization is provided by compressed air with 100% oxygen administered to the patient by using properly fitting oro-nasal masks or head tents.

A low-voltage patient intercommunication system designed and installed in accordance with NFPA 99, Chapter 19 and provides communications between the patients in the chamber and the outside chamber operator. It also provides patients with audio program content from external sources such as TV's, cassette players, radios, etc. The system consists of a master station mounted on the chamber operator's control console that contains all of the controls and connection points.

Single operator chamber pressure control is achieved via a simple programmable logic controller with output and feedback control. A pneumatic and manually operated control system is provided for triple control redundancy.

A penetrator plate is provided in the vessel wall to allow user supplied intravenous lines, medical monitoring leads, etc., to be used as required. The large rectangular door allows a normal size patient gurney to be used to transport nonambulatory patients without having to transfer the patient to a smaller litter. This feature greatly improves patient handling safety. EMT has concluded that the overall size, general design approach, method of pressure control, and intended use of the OASIS is substantially equivalent to the Tampa Hyperbaric Enterprises' Hyperbaric Chamber (K960389), the Perry Baromedical Services Sigma MP Multiplace Hyperbaric Chamber (K930748), the Gulf Coast Hyperbarics, Inc. Multiplace Hyperbaric Treatment System (K950957), the Reimers Engineering T Class Hyperbaric Facility (K954387) and is proposing them as predicate devices for the EMT OASIS.

INTENDED USE

It is the expressed, intended use of the EMT Oxygen Applied Symptom Improvement System to provide therapy to those patients with selected medical conditions that have been determined to respond to the application of hyperbaric oxygen. As a Class II prescriptive device, it is further intended for physician involvement in its procurement and routine use.

The UHMS is the professional medical organization chartered with setting the standards of care defining the appropriate use of hyperbaric oxygen. More specifically, the UHMS publishes a listing of medical conditions that have been clearly established as appropriate primary or adjunctive use of hyperbaric oxygen (HBO). The disorders on the list have been scientifically validated and verified through extensive data collection. It should be noted that the list is dynamic. Based on the strength of the scientific data, disorders are both added and removed from the list, depending on the outcomes of scientific pursuit.

The conditions listed as appropriate for the use of HBO in the current edition of the UHMS Hyperbaric Oxygen Therapy Committee Report (1999) are as follows:

1. Air or gas embolism
2. Carbon monoxide poisoning and carbon monoxide poisoning complicated by cyanide poisoning
3. Clostridial myositis and myonecrosis
4. Crush injury, compartment syndrome, and other acute traumatic ischemias
5. Decompression sickness
6. Enhanced of selected problem wounds
7. Exceptional blood loss anemia
8. Necrotizing soft tissue infections
9. Osteomyelitis (refractory)
10. Delayed radiation injury (soft tissue and bony necrosis)
11. Skin grafts and flaps (compromised)
12. Thermal burns
13. Intracranial abscess

The EMT Oxygen Applied Symptom Improvement System is designed to be installed and operated in medical facilities as defined by the NFPA 99, Health Care Facilities, Chapter 19, Hyperbaric Facilities. Further, this system is intended to be operated only by medical personnel specifically trained in the appropriate use of HBO and the safe operations of all related equipment such as the hyperbaric chamber.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2001

Mr. Don Schmieley
Engineered Medical Technology, Inc.
7303 Houston Hwy.
P.O. Box 1939
Victoria, TX 77902

Re: K001121
Oxygen Applied Symptom Improvement System
Regulation Number: 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: Class II (two)
Product Code: 73 CBF
Dated: August 31, 2001
Received: August 31, 2001

Dear Mr. Schmieley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

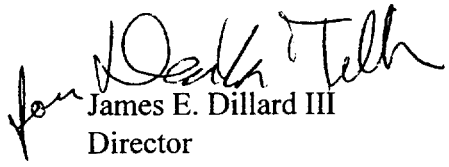
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) #: K001121

INDICATIONS FOR USE

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As a Class II device, the EMT OASIS is intended to be procured and used by physicians to treat a variety of medical conditions that respond to hyperbaric oxygen. The UHMS is the international medical organization chartered with setting the standards of care defining the appropriate use of hyperbaric oxygen. More specifically, the UHMS publishes a listing of medical conditions that have been clearly established as appropriate primary or adjunctive use of hyperbaric oxygen (HBO). The disorders on the list have been scientifically validated and verified through extensive data collection. It should be noted that the list is dynamic. Aggressive research into the beneficial effects of hyperbaric oxygen, when appropriately applied, will result in additional medical conditions being added to the list of indications by the UHMS based on the strength of the scientific data.

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Prescription ✓

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K001121